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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,460	03/23/2001	Shanaz H. Dairkee	CPMC-010/00US	6434

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EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/816,460	Applicant(s) DAIRKEE ET AL.	
	Examiner Cynthia B. Wilder, Ph.D.	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 22-25 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☐ Claim(s) _____ is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

HC

FINAL ACTION

1. Applicant's amendment filed March 7, 2005 is acknowledged and has been entered. Claims 1, 4, 6 and 11 have been amended. Claims 18-22 have been canceled. Claims 23-25 have been added. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Declaration

3. The declaration under 37 CFR 1.132 filed on March 1, 2005 is sufficient to overcome the rejection of claims 8-17 based upon the Expert's evidence and support establishing enablement of the subject matter disclosed therein.

Previous Objections and Rejections

4. The objection to the specification is withdrawn in view of Applicant's amendment to the specification. The claim rejection under 35 USC 112 first paragraph as lacking enablement is withdrawn in view of the Expert's declaration under 37 CFR 1.132. The prior art rejection under 35 USC 102(b)/103(a) is maintained and discussed below.

Claim Rejections - 35 USC § 102/103

5. Once again, claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Deng et al. (Science, Vol. 272, pages 2057-

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2059, 20 December 1996). Regarding claims 1, 2, 4-6, Deng et al teach a method comprising the steps of providing a target cell sample from a patient wherein said target cell sample comprises morphologically normal breast cells associates with a tumor, analyzing the target cell sample from a patient for loss of heterozygosity at chromosomal locus 3p22-25, classifying samples as having LOH at chromosomal locus 3p22-25 as positive, wherein a positive sample may indicate a risk of breast cancer, a likelihood of tumor reoccurrence, or more aggressive post surgical treatment (see entire reference, especially, Figure 2, Table 1 and page 2059, col. 2, last full paragraph). The preceding rejection is based on the judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because the reference is silent with regards to the chromosomal locus being at 3p24.3. However, this locus is deemed to be inherent by the reference of Deng et al. in the teaching that cells were examined for LOH at chromosome 3p22-25 which encompasses the locus 3p24.3. Additionally, Deng et al analyzed the same locus EABMD and EABH) noted by Applicant at page 17, line 1 to be within 3p24.3 (see figure 2, fourth line from bottom of legend). The Burden is on Applicant to establish that the locus of the prior art is different from that of the instant invention.

Regarding claim 3, Deng et al teach the method of claim 1, wherein the patient has undergone a surgical procedure (mastectomy) to treat said previously diagnosed cancer (page 2058, col. 3, line 2 from bottom of col.).

Regarding claim 7, Deng et al teach the method of claim 6, wherein said breast tissue is a breast tissue biopsy tissue (page 2059, reference note number 14).

Applicant's Traversal and Examiner's Response

6. Applicant traverses the rejection on the following grounds: Applicant states that the

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amendment by including the step that then identifies the LOH positive target sample to a clinician clarifies the instant invention.

This argument has been thoroughly reviewed and considered but is not found persuasive because the prior art document of Deng teaches this limitation. At page 2059, col. 2, Deng et al teaches identifying any positive samples and determining the next course of treatment or counseling. Applicant's arguments are not sufficient to overcome the prior art rejection.

Conclusion

7. Claims 1-7 are not allowed. Claims 8-17 and 23-25 are free of the prior art because no prior art was found associating the thyroid hormone receptor beta 1 to methods for determining the likelihood or re-occurrence of or post-surgical treatment of and/or risk of breast cancer in a patient. No motivation could be found in the prior art for the invention as described therein. Accordingly, an obviousness rejection against those claims could not be made.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

Kenneth R. Horlick

5/24/05